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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/919,770 | 07/31/2001 | Paul Bornstein | UOFW117618 | 4001 |

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CHRISTENSEN, O'CONNOR, JOHNSON, KINDNESS, PLLC
1420 FIFTH AVENUE
SUITE 2800
SEATTLE, WA 98101-2347

EXAMINER

GIBBS, TERRA C

ART UNIT PAPER NUMBER

1635

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/919,770

Applicant(s)

BORNSTEIN ET AL.

Examiner

Terra C. Gibbs

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28,32 and 35-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28, 32 and 35-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is a response to Applicant's Amendment and Remarks filed February 18, 2005.

New claim 37 is acknowledged. Claims 28, 32, and 35-37 are pending in the instant application.

Claims 28, 32, and 35-37 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

In the previous Office Action mailed November 23, 2004, claims 28, 32, 35, and 36 were rejected under 35 U.S.C. 102(e) as being anticipated by Streit et al. [U.S. Publication No: 2002/0119921]. **This rejection is maintained** for the reasons of record set forth in the previous Office Action mailed November 23, 2004. It is noted that new claim 37 is also included in this rejection.

Response to Arguments

In response to this rejection, Applicants argue that Streit et al. do not teach each and every element of the claimed invention. For example, Applicants argue that Streit et al. do not disclose an implantable medical device comprising antisense thrombospondin-2 (TSP-2) nucleic acid molecules, or the use of an implantable medical

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device, comprising antisense thrombospondin-2 nucleic acid molecules, to locally decrease the amount or biological activity of thrombospondin-2 in an animal. It is noted that Applicants acknowledge that Streit et al. disclose methods for decreasing TSP-2 activity, but Applicants argue that Streit et al. do not disclose the TSP-2 activity can be decreased by introducing antisense TSP nucleic acid molecules in association with a controlled release device, or some other implantable device.

Applicants arguments have been fully considered but are not found persuasive because contrary to Applicants arguments, Streit et al. disclose that TSP-2 activity can be decreased by introducing antisense TSP-2 nucleic acid molecules in association with a controlled release device, or some other implantable device. For example, Streit et al. disclose at paragraph [0049], "TSP-2 activity is decreased, e.g., by administering an agent which decreases a TSP-2 activity. An agent which decreases a TSP-2 activity can be one or more of: a TSP-2 nucleic acid molecule, e.g., an antisense molecule". Streit et al. also disclose at paragraph [0181], "An agent which modulates TSP-2 activity, e.g., nucleic acid molecules, TSP-2 polypeptides, fragments or analogs, TSP-2 modulators, and anti-TSP-2 antibodies (also referred to herein as "active compounds") can be incorporated into pharmaceutical compositions suitable for administration". Streit et al. further disclose at paragraph [0189], "The active compounds are prepared with carriers that will protect the compound against rapid elimination from the body, such as a controlled release formulation, including implants and microencapsulated delivery systems". Therefore, Streit et al. clearly anticipate the instant claims.

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Streit et al. also anticipate new claim 37. Claim 37 is drawn to a method of locally decreasing the amount or biological activity of thrombospondin 2 in an animal comprising administering antisense TSP-2 nucleic acid molecules in association with a medical device, wherein decreasing the amount or biological activity of thrombospondin 2 decreases the foreign body reaction against the medical device. It is noted that the claim recites only one method step, namely administering an antisense TSP-2 nucleic acid molecule in association with a controlled release device in an animal. It is further noted that this method step results in decreasing the amount or biological activity of thrombospondin-2, which results in decreasing the foreign body reaction against the medical device. Streit et al. disclose the one method step recited in the instant claims. Streit et al. further disclose decreasing the amount or biological activity of thrombospondin-2 in an animal. Therefore, the foreign body reaction against the medical device would *inherently* be decreased in the method disclosed by Streit et al., absent evidence to the contrary. For further explanation, the Examiner would like to direct Applicants to MPEP 2112 [R2] where it states:

"The express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102 or 103. "The inherent teaching of a prior art reference, a question of fact, arises both in the context of anticipation and obviousness." In re Napier, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir. 1995) (affirmed a 35 U.S.C. 103 rejection based in part on inherent disclosure in one of the references). See also In re Grasselli, 713 F.2d 731, 739, 218 USPQ 769, 775 (Fed. Cir. 1983)".

"Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. "There is nothing inconsistent in

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concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." In re Best, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). **This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic.** Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims."

Therefore, Streit et al. anticipate the instant claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wang Andrew can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

tcg

May 3, 2005

A handwritten signature in black ink, appearing to read 'Andrew Wang', is positioned above the printed name and title.

ANDREW WANG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600